AWARD NUMBER: W81XWH-12-1-0557

TITLE: Identifying Immune Drivers of Gulf War Illness Using a Novel Daily Sampling Approach

PRINCIPAL INVESTIGATOR: Jarred Younger, PhD

CONTRACTING ORGANIZATION: University of Alabama at Birmingham
Birmingham, AL 35294-0111

REPORT DATE: October 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2016	Annual	30 Sep 2015 - 29 Sep 2016

4. TITLE AND SUBTITLE

Identifying Immune Drivers of Gulf War Illness Using a Novel Daily Sampling Approach

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-12-1-0557

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Jarred Younger, PhD.
Kate Wesson Sides, Program Coordinator II

E-Mail: younger@uab.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Alabama at
Birmingham-UAB
AB 1170
1720 2nd Avenue South
Birmingham, AL 35294-0111

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Since the last annual report, we have initiated participant screening, participant enrollment and the study protocol.

All start up subtasks have been completed. To date 131 potential participants have filled out the online screening questionnaire, seventy of those have been screened by phone, and fourteen have been enrolled in the study.

Fifteen participants are scheduled to begin the study protocol in January 2017 and screening for a spring cohort is currently underway.

Screening and enrollment will continue as we work toward completing this study.

15. SUBJECT TERMS
Gulf War Illness, cytokines, microglia, daily, immune, phlebotomy, fibromyalgia

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	6	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

1. INTRODUCTION:

The major aim of this research project is to identify aspects of the immune system that are dysregulated in veterans with Gulf War Illness (GWI). A second aim is to determine whether identified immune system dysregulations are similar to those found in men with Fibromyalgia. To accomplish those aims at UAB, we are recruiting 29 male veterans diagnosed with GWI, as well as 2 healthy veteran controls, and 4 males with Fibromyalgia/Chronic Fatigue Syndrome (FM/CFS). Participants will complete 25 consecutive days of blood draws and provide daily reports of symptom severity. Analyses will then be conducted to identify immune system factors that correlate with day-to-day symptom fluctuations in the participants. Ultimately, this information may be used to develop new treatments that specifically target the pathophysiological mechanisms of Gulf War Illness.

(Note: A complete analyzed data set will consist of the data collected from the 22 participants at Stanford University and the 35 participants at UAB).

2. KEYWORDS:

Gulf War Illness, cytokines, microglia, daily, immune, phlebotomy, fibromyalgia

3. OVERALL PROJECT SUMMARY:

Current Objectives:

· Continue recruitment and data collection at UAB

· Complete the protocol on 35 participants.

Results, Progress and Accomplishments

Task 1: Team review and progress meetings

60% Completed.

(Note: The analysis planning meeting in the revised SOW has been rescheduled to allow time to complete data collection from the 35 participants that will be enrolled at UAB).

Task 2: Submission of Documents for Regulatory Approvals

100% Completed.

Task 3: Start up Machine/Personnel

100% Completed

Task 4: Advertisement

75% Completed. New recruitment tools have been launched and are actively on-going.

Advertisements via the UAB campus/local newspaper and website are on-going.

Radio advertisements were aired May 2, 2016 – May 27 2016 and August 8, 2016 – September 8, 2016, these will resume in 2017. These were an excellent avenue to reach the potential participants.

Task 5: Enroll GWI Participants for Study

35% Completed. Ten GWI participants have been enrolled. We will continue recruitment in January 2017.

(Note: The reported percentage is a representation for the SOW at UAB.)

Task 6: Recruit Control Groups

50% Completed. Will continue recruitment in January 2017, 1 of the 2 healthy controls have completed the protocol and 2 of the 4 Fibromyalgia participants have completed the protocol, the remaining will be enrolled in 2017.

Task 7: Run Protocol

23% Completed. Further progress is dependent on completing Tasks 5 and 6.

Task 8: Quantification of bio-chemicals in blood samples

0% Completed. Further progress is dependent on completing Task 7.

Task 9: Analyses

0% Completed. Further progress is dependent on completing Tasks 7 and 8.

Task 10: Preparation of final report and publications

0% Completed. This task is contingent on completion of Tasks 7, 8, and 9.

Key methodology:

We have used the methodology outlined in other submitted documents. As stated in the SOW, we have recruited participants from a variety of sources, including local advertisements. We have performed the study protocol exactly as described in the SOW. Eight individuals have completed the protocol.

Research Conclusions:

Because we have not completed the data collection, we have nothing to report.

Actual or anticipated problems or delays:

Nothing to report.

Changes to Approach:

We are not proposing any changes to the approach.

KEY RESEARCH ACCOMPLISHMENTS:

Nothing to report.

4. INVENTIONS,PATENTS AND LICENSES:

Nothing to report.

5. **PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:**

Nothing to report.

6. **INVENTIONS, PATENTS AND LICENSES:**

Nothing to report.

7. **REPORTABLE OUTCOMES:**

Nothing to report.

8. **OTHER ACHIEVEMENTS:**

Nothing to report.

9. **REFERENCES:**

No references.

10. **APPENDICES:**

No appendices.